

REMARKS

I. Claim Rejections under 35 U.S.C. § 112

Claims 27-35 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. As an initial matter, Applicant respectfully submits that the test for § 112, first paragraph, is not whether a specific word is used in the specification. Rather, the test is whether the applicant has possession of the claimed subject matter in view of the specification.

According to the Office Action, the specification does not describe an outer sheath that has a distal tip for dissecting tissue, as described in claim 27. Applicant respectfully notes that at least figures 5 and 6, and their corresponding description (e.g., paragraphs 15, 16) describes embodiments of an outer sheath that has a distal tip for dissecting tissue. Thus, Applicant respectfully submits that claim 27 should satisfy § 112.

Claim 29 recites that the distal tip is fixedly secured to a distal end of the outer sheath. Support for these limitations can be found at least in figures 5 and 6, which illustrate the distal tip being secured to the distal end of the outer sheath to thereby fix the position of the distal tip relative to the outer sheath. Thus, Applicant respectfully submits that claim 29 should satisfy § 112.

Claim 31 recites that the expansion device is housed within a lumen of the outer sheath, and is prevented from moving distal to the distal tip of the outer sheath. Support for these limitations can be found at least in figures 5 and 6, which show that the expansion device within the outer sheath is proximal to the distal tip, and cannot be moved past the distal tip (because the

distal tip has a closed end). Thus, Applicant respectfully submits that claim 31 should satisfy § 112.

II. Claim Rejections under 35 U.S.C. § 103

Claims 15, 21-23, 25-31, and 34-35 stand rejected under 35 U.S.C. § 103 as allegedly being unpatentable over U.S. Patent No. 5,318,588 (Horzewski) in view of U.S. Patent No. 6,264,670 (Chin).

Claim 15

Claim 15 recites an elongated instrument having *a distal tip configured to dissect tissue* (Emphasis Added). According to the Office Action, Horzewski allegedly discloses a distal tip 127 configured to dissect tissue. However, Applicant respectfully notes that the element 127 of Horzewski is a “bulbous region” that is configured to expand an outer sheath (column 12, line 63 to column 13, line 18). There is nothing in Horzewski that discloses or suggests that the bulbous region is configured to dissect tissue, as described in claim 15.

Claim 15 also recites that the distal tip is transparent. According to the Office Action, Chin discloses a transparent tip, and it would have been allegedly obvious to provide the transparent tip of Chin for the device of Horzewski. Applicant respectfully traverses. As an initial matter, Applicant respectfully notes that the device of Horzewski already has a through lumen with a distal opening, which could already provide viewing by an endoscope. Therefore, to the extent that the bulbous region 127 is analogized as the claimed distal tip, making the bulbous region 127 transparent would not enable any more viewing than what the device can

already accomplish. Thus, the purported reason of providing viewing cannot be the motivation to make the bulbous region 127 transparent.

Also, to the extent that it is suggested in the Office Action that the transparent tip of Chin be used to replace the bulbous region 127, Applicant respectfully notes that such purported modification would render the device of Horzewski inoperable. This is because Horzewski teaches a device with a through lumen so that a guidewire can extend therethrough (column 10, lines 30-36; column 12, lines 46-55). Placing the tip of Chin on Horzewski's device would prevent the guidewire from extending through the sheath. Also, the device of Horzewski requires the bulbous region 127 to have an expansion taper 124 (column 12, lines 65-68), so that withdrawal of the bulbous region 127 can cause an expansion of the outer sheath via the taper 124. The tip of Chin cannot achieve such function. Thus, the purported modification of the device of Horzewski would contradict the teaching of Horzewski, and would render the device of Horzewski inoperable for its intended purpose. Note that a prima facie case of a § 103 rejection cannot be established if a purported modification would render a device in a reference operable, or if it contradicts a teaching of a reference.

For at least the foregoing reasons, claim 15 and its dependent claims should be allowable over Horzewski, Chin, and their combination.

Claim 27

Claim 27 recites an apparatus that includes an elongated instrument having an expansion device, and an outer sheath disposed about at least a portion of the elongated instrument, the outer sheath having a distal tip for dissecting tissue. Horzewski and Chin do not disclose or suggest the combination of the above limitations.

Rather, Horzewski discloses a dilator 150 with a bulbous region 127 (figure 6B), with a sheath 90 surrounding the dilator 150 (figure 5A). Notably, to the extent that the bulbous region 127 of Horzewski is analogized as the claimed distal tip, the bulbous region 127 is a part of the dilator 150, not the sheath 90. Thus, Horzewski clearly does not disclose or suggest an outer sheath having a distal tip for dissecting tissue, as described in claim 27.

Chin also does not disclose or suggest the combination of the above limitations, and therefore fails to make up the deficiencies present in Horzewski. Since both Horzewski and Chin do not disclose or suggest the combination of the above limitations, any purported combination of these references cannot result in the subject matter of claim 27.

Also, Applicant notes that the Office Action has not specified which elements of claim 27 are purported to be met by which elements in the Horzewski and Chin references. Thus, to the extent that the Examiner is inclined to maintain the § 103 rejections for claim 27, Applicant respectfully requests that the Examiner indicate which elements from the cited references are being analogized as the claimed features.

Furthermore, to the extent that the Office Action appears to suggest that the tip of Chin be used to replace the bulbous region 127 (which the Examiner analogized as the claimed “tip”) of Horzewski, Applicant submits that there is no proper motivation for such purported modification, and such purported modification would render the device of Horzewski inoperable, as discussed. For at least the foregoing reasons, claim 27 and its dependent claims should be allowable over Horzewski, Chin, and their combination.

CONCLUSION

Based on the foregoing remarks, all claims are believed allowable. If the Examiner has any questions or comments regarding this response, the Examiner is respectfully requested to contact the undersigned at the number listed below.

To the extent that any arguments and disclaimers were presented to distinguish prior art, or for other reasons substantially related to patentability, during the prosecution of any and all parent and related application(s)/patent(s), Applicant(s) hereby explicitly retracts and rescinds any and all such arguments and disclaimers, and respectfully requests that the Examiner re-visit the prior art that such arguments and disclaimers were made to avoid.

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Respectfully submitted,

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